

1 WHAT IS CLAIMED IS:  
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- 3 1. An active agent dosage form adapted for gastric retention  
4 comprising: (a) a first layer comprising a swellable, water-soluble polymer;  
5 (b) a second layer comprising a therapeutically-effective amount of an active  
6 agent, the second layer being laminated with the first layer at a common  
7 surface, and (c) at least one band of insoluble material circumscribing and  
8 binding together the first layer and the second layer, the first layer being  
9 adapted to swell in the stomach to facilitate retention of the dosage form in  
10 the stomach over a prolonged period of time, wherein the release of the  
11 active agent from the second layer is independent of the composition of the  
12 first layer and occurs over a prolonged period of time.
- 13
- 14 2. The active agent dosage form of claim 1 wherein the number  
15 average molecular weight of the water-soluble polymer is between about  
16 100,000 and 20,000,000 grams per mole.
- 17
- 18 3. The active agent dosage form of claim 2 wherein the water  
19 soluble polymer is polyethylene oxide, hydroxypropyl cellulose, hydroxypropyl  
20 methyl cellulose, hydroxyethyl cellulose, sodium carboxy methylcellulose,  
21 calcium carboxymethyl cellulose, methyl cellulose, polyacrylic acid,  
22 maltodextrin, pre-gelatinized starch, guar gum, sodium alginate, or polyvinyl  
23 alcohol.
- 24
- 25 4. The active agent dosage form of claim 1 wherein the second  
26 layer comprises a hydroattractant selected from low-substituted hydroxypropyl  
27 cellulose, microcrystalline cellulose, cross-linked sodium or calcium  
28 carboxymethyl cellulose, cellulose fiber, cross-linked polyvinyl pyrrolidone,  
29 cross-linked polyacrylic acid, cross-linked Amberlite resin, alginates, colloidal  
30 magnesium-aluminum silicate, corn starch granules, rice starch granules,  
31 potato starch granules and sodium carboxymethyl starch, sugars, sodium

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1 chloride, and the first layer optionally comprises a hydroattractant selected  
2 from low-substituted hydroxypropyl cellulose, microcrystalline cellulose, cross-  
3 linked sodium or calcium carboxymethyl cellulose, cellulose fiber, cross-linked  
4 polyvinyl pyrrolidone, cross-linked polyacrylic acid, cross-linked Amberlite  
5 resin, alginates, colloidal magnesium-aluminum silicate, corn starch granules,  
6 rice starch granules, potato starch granules, sodium carboxymethyl starch,  
7 sugars and sodium chloride.

8  
9 5. The active agent dosage form of claim 1 wherein the first layer  
10 swells more rapidly and to a greater extent than does the second layer.

11  
12 6. The active agent dosage form of claim 5 wherein the active  
13 agent is an antiviral, antimicrobial, antidiabetic, antihyperglycemic,  
14 hypoglycemic, antidepressant, antiobesity or antifungal active agent.

15  
16 7. The active agent dosage form of claim 4 wherein the weight  
17 percent of the water soluble polymer in the second layer is 5 to 99.99 weight  
18 percent and weight percent of the hydroattractant in the second layer is 0 to  
19 60 weight percent.

20  
21 8. The active agent dosage form of claim 1 wherein the prolonged  
22 time period is at least 3 hours.

23  
24 9. The active agent dosage form of claim 1 wherein the time period  
25 is between about 6 to 12 hours.

26  
27 10. The dosage form of claim 1 wherein the first layer comprises  
28 polyethylene oxide having a number average molecular weight of at least  
29 100,000 grams per mole.

30  
31 11. The dosage form of claim 10 wherein the active agent is an

antiviral, antimicrobial, antidiabetic, antihyperglycemic, hypoglycemic, antidepressant, antiobesity or antifungal active agent.

12. The dosage form of claim 11 wherein the active agent is acyclovir, ganciclovir, ritonavir, minocycline, cimetidine, ranitidine, captopril, methyldopa, selegiline, minocycline, fexofenadine, metformin, bupropion, orlistat or a pharmaceutically acceptable salt thereof.

13. The dosage form of claim 10 wherein the active agent is metformin or a pharmaceutically acceptable salt thereof.

14. The dosage form of claim 1 wherein the second layer comprises an active agent selected from the group consisting of acyclovir, ganciclovir, ritonavir, metformin, bupropion, orlistat and minocycline, and the second layer comprises a bioerodible polymer, wherein the dosage form releases a therapeutically effective amount of the active agent to the stomach of a subject over at least a 3 hour period.

15. A method of treating a subject in need thereof with an active agent that comprises administering to the subject a multilayered dosage form adapted to be retained in the stomach over a prolonged period of time, the dosage form comprising a first layer adapted to swell in the stomach of the subject and retain the dosage form in the stomach for a prolonged period of time, and a second layer adapted to deliver to the subject an active agent at a variable rate of delivery.

16. The method of claim 15 which comprises administering one or more dosage forms to the subject in the fed state at the start of each dosing period.

17. The method of claim 16 wherein the administration of the

dosage form occurs within one hour of the subject consuming food.

18. The dosage form of claim 1 comprising a gastric-emptying delaying agent.

19. The dosage form of claim 18 wherein the gastric-emptying delaying agent is selected from anticholinergic agents, methylcellulose, guar gum, fats and fatty acids of 10-15 carbon atoms.

20. The dosage form of claim 1 wherein the active agent comprises a liquid, active agent formulation.

21. The dosage form of claim 20 wherein the liquid, active agent formulation is sorbed into porous particles.

22. The dosage form of claim 21 wherein the porous particles are calcium hydrogen phosphate or magnesium aluminometasilicate.

23. The dosage form of claim 1 wherein the dosage form comprises a pH regulating agent.

24. The dosage form of claim 21 wherein the liquid, active agent formulation comprises a pH regulating agent selected from organic and inorganic acids and bases.

25. The dosage form of claim 21 wherein the liquid, active agent formulation comprises a chelating agent.

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